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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,884	BAKER, MATTHEW JOHN	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03 Augsut 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The objection to the specification as found at paragraphs 2-5 of the Office action mailed 05 March 2004 have been withdrawn in view of applicant's amendments.

Claims

2. The objection to the claims as found at paragraphs 6 and 7 of the Office action mailed 05 March 2004 have been withdrawn in view of applicant's amendments.

3. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

4. A claim, which depends from a dependent claim, should not be separated by any claim, which does not also depend from said dependent claim. In the present case, claim 32 is separated from independent claim 1 by independent claims 25, 26, and 31. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

5. Claims 28-30 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 27 stipulates the placement of the solid phase, and that being "within the barrel of the syringe." Claims 28-30, however, effectively broaden the scope of claim 27 by stipulating that the solid phase is located external to the barrel of the syringe.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

8. Claims 1-25 and 32-37 are drawn to a method for extracting nucleic acid. Claims 26-31, 38, and 39 are drawn to an extraction device from extracting nucleic acid from a liquid mixture. For convenience, independent claims 1 and 26 are reproduced below.

1. (Currently amended) A method for extracting nucleic acid from a liquid mixture containing nucleic acid, the liquid mixture comprising a biological or a biochemical sample, the method comprising providing a container having a first and second end and containing a solid phase capable of binding nucleic acid and a reversible suction means connected to one of said ends; and (b) operating said reversible suction means to draw the liquid mixture through the solid phase in one direction and forcing the liquid mixture over the solid phase in the reverse direction, so that nucleic acid in the sample binds to the solid phase.

26. (Currently amended) An extraction device for extracting nucleic acid from a liquid mixture containing nucleic acid, the liquid mixture comprising a biological or a biochemical sample, the device comprising (a) a container having first and second ends and containing a solid phase capable of binding nucleic acid and (b) reversible suction means which is connected to one of said ends and operates to draw the liquid mixture through said solid phase in one direction and force said liquid through said solid phase in the reverse direction, thereby causing said liquid mixture to pass up and down through said solid phase.

9. In addressing the claimed method of extracting nucleic acids from a liquid, it is noted with particularity that the method of claims 1-4, 6-25, and 32-37 fairly encompass eluting any bound nucleic acid in the reverse direction of which the crude sample was last passed through the device without any washing step being performed, the end result being that any crude material that was located in the device would be reintroduced to the now eluted nucleic acids.

10. The method of claims 1-18, 21-25, and 32-36 also fairly encompasses having no means of retaining or directing the placement of the requisite "solid phase." With the "solid phase" being a bead or some other highly moveable surface, the solid surface, a well as any contaminant would be reintroduced into the final preparation of nucleic acids.

11. The specification fails to provide an adequate written description of how any liquid mixture comprising a biological or biochemical mixture is to be extracted from any contaminant with the very method allows for the retention, if not remixing, of the very contaminants with that which one seeks to extract or otherwise isolate and elute (claim 6).

12. A review of the disclosure finds 15 examples.

- Example 1, page 11; nuclei, not DNA or RNA, are isolated onto beads;
- Example 2, pages 11, nuclei not nucleic acids, are isolated onto beads, with nuclei being subsequently subjected to boiling alkaline detergent treatment and elution of DNA;
- Example 3, page 12; alkaline lysis preparation of an unidentified plasmid sample was applied to beads at pH 5 and eluted at pH 9.
- Example 4, page 12, nuclei were isolated from whole blood cells
- Example 5, "Purification of buccal cell DNA," pages 12-13;
- Example 6, capture of nuclei of blood cells on beads that are subsequently lysed and DNA captured on "porous disc;"
- Example 7, page 13, "Removal and purification of human IgG from serum;"
- Example 8, page 14, "Purification of specific white blood cell types from whole blood;"
- Example 9, page 14, "Recombinant protein purification;"
- Example 10, page 14, "Extraction of HIV RNA from serum;"

- Example 11, page 14, "Purification of PCR reactions;"
- Example 12, pages 14-15, "Extraction of RNA from Liver;"
- Example 13, "Isolation of mRNA" using COOH polystyrene beads coupled to oligo-dT 30 5' NH_2;
- Example 14, page 15, "Streptavidin immobilized on solid-phase" used to capture biotinylated primers and PCR product;
- Example 15, pages 15-16, "Use of electrodes, static charge, induction, electrophoresis to isolate DNA or RNA" (12 V DC battery used to capture nuclei or DNA on surface of dialysis tubing).

Of the above examples, Examples 1-6 and 10-15 are relevant to the claimed invention. As seen therein, none of the examples describe the application of untreated sample to beads whereby DNA or RNA is isolated without performance of an extraction step. Further, no description is provided as to the extraction of DNA or RNA from an organic sample, e.g., crude oil, or from bone or any plant material. While the claims have been amended so to recite that the sample is "liquid" as well as being "biological" or "biochemical," the claimed method and claimed device both fairly encompass the "extraction" of nucleic acids where the "biochemical" sample is virtually any sample that contains any biochemical, including extracting nucleic acids from bacteria found and introduced into crude oil, be it an oil spill or in an oil well where one is attempting to enhance recovery of oil from shale. The specification does provide a description of extracting DNA from blood samples.

The specification does not provide any description as to how any nucleic acid would be isolated form cells associated with bone material (e.g., osteoclasts, osteoblasts, etc.), when the bone has

been pulverized and is in a liquid sample, which would lead to blockage of pores of beads, membrane, frit, etc.

13. While an example does describe the extraction of plasmids, there is no clear indication as to what type of sample was being used.

14. Acknowledgement is made of applicant's remarks wherein it is asserted that nucleic acids can be recovered from an amplification reaction (page 22 of the response of 03 August 2004). As an initial matter, it is noted with particularity that in stark contrast to applicant's assertions, Example 3 does not teach isolation from a sample that has not been subjected to any extraction. Rather, Example 3 (page 12 of the specification) teaches isolation of plasmid DNA subsequent to cells undergoing alkaline lysis.

15. Applicant's remarks as to extraction of nucleic acids from an amplification reaction fail to address how and where the specification describes such a procedure when PCR is performed where the sample is overlaid with an oil so to preclude evaporation, and where the oil will be drawn into the device and foreseeably, retard if not proscribe the binding of nucleic acids to the solid phase, now covered/coated with an oil. Assuming *arguendo* that the claims were to be directed to the isolation of PCR reactants, for which Example 14 is relevant, neither template DNA or RNA was extracted onto a solid phase, but rather, biotinylated primers were bound to a streptavidin-coated porous frit, and then under specific conditions. See Example 14, *infra*.

Example 14 Streptavidin immobilised on solid-phase

Streptavidin was immobilised onto porous frits by mixing the protein in 0.1 M sodium phosphate buffer with 0.01% glutaldehyde pH7 as in example 4. Biotinylated primers used to generate a PCR product were then isolated on the immobilised streptavidin. The PCR product was then made single stranded using heat or 0.1 M NaOH and used for sequencing or probe analysis.

16. The specification does not provide an adequate written description of alternative methodologies or of alternative devices to be used in such a manner.

17. While one may assert that it would be obvious to one of skill in the relevant art to modify or adapt the disclosure so to isolate nucleic acids from other sources, obviousness cannot be relied upon for satisfaction of the written description requirement of 35 USC 112, first paragraph. It would appear that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

18. To the extent that the claims encompass pores of any dimension (e.g., claim 20), a review of the disclosure fails to locate an adequate written description of such embodiments. Rather, page 5 of the disclosure provides support for pores that range from 1 micron to 150 microns. A review of the disclosure fails to locate an adequate written description of pores of some other dimension.

19. To the extent that the claims encompass an extraction device that comprises a by-pass channel, page 8 of the disclosure teaches that the channel is a tube used with glass beads smaller than 100 microns that have a pore diameter of 20 microns or greater. A review of the disclosure fails to find an adequate written description of alternative embodiments. Accordingly, the specification does not reasonably suggest that applicant, at the time of filing, had possession of

alternative embodiments of a by-pass channel. Further, the specification does not reasonably suggest that even when used, not more than one by-pass channel is to be present.

20. Applicant's representative, at page 23 of the response, asserts:

> Finally, the "reverse flow" of the present extraction method forces any debris, particulate, viscous matter, and other waste starting materials back out of the solid phase in the reverse direction, so that it is easily disposed of, (while leaving the nucleic acids immobilized on the solid support, as disclosed at page 2, lines 26 to 30).

21. The above argument has been fully considered and has not been found persuasive towards withdrawal of he rejection. While the claimed method requires the application of "reversible suction means," the method does not require the removal or separation of any portion of the liquid sample for the device used to extract nucleic acids therefrom. Accordingly, applicant is arguing limitations not found in the claims. As noted above, claims 1-4, 6-25, 32-37 place no requirement that any wash step be performed, and that claims 1-18, 21-25, and 32-36 do not require any presence of a means for retaining the solid phase in one portion of the device while allowing the liquid sample to be discarded. Indeed, none of the method claims require the sample to ever be discarded.

22. For the above reasons, and in the absence of convincing evidence to the contrary, the specification does not provide an adequate written description of the full scope of the claimed invention and as such, does not reasonably suggest that applicant was in possession of the claimed method at the time of filing.

23. In addressing claims 26-31, 38, and 39, it is noted that there is virtually no minimal volume of a sample that can be effectively treated by the device. A review of the specification, however, fails to find an adequate written description of such a device. It is further noted that

claims 26-31 and 38 do not require the solid phase be retained within the device during operation. A review of the specification fails to find an adequate written description of how such a device is to be reproducibly made and used.

24. In accordance with claim 27, "the solid phase is located within the barrel of the syringe." Dependent claim 28, however, requires the solid phase be "located within a cartridge releasably connected to the nozzle of the syringe;" and dependent claim 29 requires "the solid phase [be] located within the tip of the pipette." Aside from raising issues under 35 USC 112, fourth and second paragraphs, the specification has not been found to provide an adequate written description of where a solid phase is be "located within a cartridge releasably connected to the nozzle of the syringe" and yet can be "located within the barrel of the syringe" and/or be in a pipette. Furthermore, a review of the specification fails to find an adequate written description of just how such a device is to be used in a meaningful and reproducible manner.

25. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

26. Claims 1-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is well settled that one cannot enable that which they do not yet possess. As presented above, the specification does not provide an adequate written description of the claimed invention, and in so failing, does not reasonably suggest that applicant was in possession of the

now-claimed invention at the time of filing. Accordingly, the same specification does not enable the scope of the claimed method, nor enable the making and use of he claimed device.

At page 27 of the response applicant's representative presents conclusory remarks as to the level of effort needed. This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

Page 27, last paragraph, of the response asserts further "all of the applicant's method claims call for extracting nucleic acid from a liquid mixture containing same." It is noted further, however, that claims 1-3, 6-25, and 32-37 do not require the sample liquid to not remain in contact with the nucleic acid, which could be bound to a solid phase. Even in the rare claim, which requires the presence of a frit or porous membrane to be present, the claimed method and device are construed to encompass pore sizes sufficiently large so as to permit cell debris to pass into the area of the "solid phase."

27. While applicant's representative has presented argument that the claimed method and device can be used to isolate DNA from an amplification reaction, the specification does not teach a reproducible procedure where such was performed without the binding being based on the affinity between streptavidin on a frit and biotinylated primers. While the specification may

well disclose various embodiments, the clams are read as broadly as is reasonably possible, and limitations found in the specification are not read into the claims.

28. Argument is presented at page 28 that the specification teaches use of dialysis tubing in preparing a blood sample whereby DNA was captured on dialysis tubing surrounding an electrode. None of the claims, be they drawn to a device or to a method, have been found to recite the method steps of Example 15. As noted above, limitations found in the claims have not been read into the claims. Rather, the specification has been reviewed to determine if the complete scope encompassed by the claims has been enabled. Such a full, clear, and concise disclosure has not been found. Therefore, and in the absence of convincing evidence to eh contrary, claims 1-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

29. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

30. Claims 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

31. Claims 28-30 all depend from claim 27, which stipulates, "the solid phase is located within the barrel of the syringe. Claim 28, however, seemingly contradicts claim 27 in that the solid phase is to be within "a cartridge releasably connected to the nozzle of the syringe," and claims 29-30 stipulate that the solid phase is "located within the tip of [a] pipette." It is unclear how the same solid phase can be in more than one place.

Claim Rejections - 35 USC § 102/103

32. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

33. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

34. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

35. Claims 1-39 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over *GIBCO BRL Products & Reference Guide* (page 20-15, 1997; GIBCO).

36. GIBCO offers for sale "NACS™-52 PREPAC™ Columns." The columns are advertised as being used in the isolation of nucleic acids from liquid samples. The product is also described as being designed so to be used with a pipette or syringe, applicant's "reversible suction means." As seen in the advertisement, the nucleic acid is "recovered" from the column. Accordingly, the

devise, and the related method of using same, are considered to meet the limitation of extracting nucleic acid from a biological or biochemical liquid sample.

37. If the product and method of using said product do not anticipate the claimed invention, a position that the Office does not concede, said disclosure is considered, in the absence of convincing evidence to the contrary, to render obvious the presently claimed method and device.

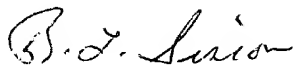
Conclusion

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

39. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

40. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
11/16/2004